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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/482,653	01/13/2000	JOHN A. WELLS	70869-0078	7295
22902	7590	01/14/2002	EXAMINER	
CONRAD J. CLARK CLARK & BRODY 1750 K STREET NW SUITE 600 WASHINGTON, DC 20006			COOLEY, CHARLES E	
ART UNIT		PAPER NUMBER		10
1723				

DATE MAILED: 01/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action SummaryApplication No.
09/482,653

Applicant(s)

Wells, Deceased et al.

Examiner

Charles Cooley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 Sep 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-37 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-37 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

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OFFICE ACTION

1. This application has been assigned to Technology Center 1700, Art Unit 1723

and the following will apply for this application:

a. Please direct all written correspondence with the correct application serial number for this application to Art Unit 1723.

b. Telephone inquiries regarding this application should be directed to the Technology Center 1700 receptionist at ~~(703)~~ 308-0651 or to the Examiner at ~~(703)~~ 308-0112. Official facsimile correspondence filed before a final office action should be transmitted to ~~(703)~~ 872-9310. Official facsimile correspondence which responds to a final office action should be transmitted to ~~(703)~~ 872-9311.

c. Inquiries regarding application status, matching responses with applications, patent term questions, locating and retrieval of applications, incomplete office actions, requests for copies of office actions and/or references, requests to remail office actions, small/large entity status, or other administrative inquiries should be directed to the **Technology Center 1700 Customer Service Center** at ~~(703)~~ 306-5665.

Assignee

2. Receipt is acknowledged of a Consent of Assignee and Statement under 37 CFR 3.73(b) filed 29 OCT 2001.

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Inventorship

3. The requirement for proof of authority of the legal representative for deceased inventor John A. Wells is withdrawn in view of the new rules which no longer requires such proof.

Surrender of Patent

4. The offer to surrender the original patent is acknowledged. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Reissue Oath/Declaration

5. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

- a. It does not identify the citizenship of each inventor (37 CFR 1.63(a)(3)).
- b. It does not state whether the inventor is a sole or joint inventor of the invention claimed (37 CFR 1.63(a)(3)).
- c. It appears the name of the first inventor is actually --John R. Wells-- rather than "John A. Wells".
- d. Is item (4) of the declaration missing data? (by any amendment on _____).

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6. Claims 1-37 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

Drawings

7. Requirements for drawings in reissue applications are found in 37 CFR 1.174 and MPEP 1413.

Specification

8. The abstract is acceptable.
9. The amended title of the invention is acceptable.

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Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 22, 23, 24, 25, 28, and 29 are rejected under 35 U.S.C. § 102(b) as being anticipated by Raccuglia et al.

The patent to Raccuglia et al. discloses a system in Figs. 8-11 comprising a centrifuge 212; a walled container 110, 112 (Figs. 8-9) having a first chamber 114 and a second chamber 116; a bridge 164, 153, 152, 138 for transferring fluid between the chambers; a holder assembly 214 attached to the centrifuge for removably receiving the container; lid portions 120, 122; access port 118; pivotally mounted frame 216.

12. Claims 25-27 are rejected under 35 U.S.C. § 102(e) as being anticipated by Li.

The patent to Li discloses a walled container 12 comprising a first chamber 16 and a second chamber 40; a bridge 34 for transferring fluid between the chambers (Figs. 3-8); a removable lid C; and access port 26.

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13. Claims 25-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by McFarland.

The patent to McFarland discloses a walled container (Fig. 1) comprising a first chamber 12 and a second chamber 14; a bridge 32; a removable lid 18; and access port (proximate 22).

14. Claims 33 and 36 are rejected under 35 U.S.C. § 102(b) as being anticipated by McFarland.

The patent to McFarland discloses a walled container (Fig. 3) comprising a first chamber 12A and a second chamber 14A; a bridge 62; lid 66; access ports 70; and separation disks 38.

15. Claims 25-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Crippa.

The patent to Crippa discloses a walled container comprising a first chamber 1 and a second chamber 7; a bridge 4 (Fig. 4); a removable lid 10; and access port (proximate 6).

16. Claims 33 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Crippa.

The patent to Crippa discloses a walled container comprising a first chamber 1 and a second chamber 7; a bridge 4 (Fig. 4); a lid 10; access ports (proximate 3 and 6); the bridge 4 being formed at the tops of the adjacent sidewalls of the chambers (Fig. 4).

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17. Claims 25-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Onishi.

The patent to Onishi discloses a walled container in Fig. 2 comprising a first chamber A and a second chamber B; a bridge 21a; a removable lid 23 or 25; and access ports 22 and 24.

18. Claims 33, 34, 35, and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Onishi.

The patent to Onishi discloses a rigid walled container of a suitable material (Col. 3, lines 36-39) in Fig. 2 comprising a first chamber A and a second chamber B; a bridge 21a; a removable lid 23 or 25; access ports 22 and 24; the bridge 21a being formed at the tops of the adjacent sidewalls of the chambers (Fig. 2).

* * *

With regard to the above rejections, the operational and functional language of the claims (e.g., "wherein the holder assembly is effective to position the container on one or more predetermined positions" (claim 22) or "such that a substance can be transferred from the first chamber to the second chamber while the container is positioned at a predetermined angle" (claim 25), etc.) has been considered but fails to impart or invoke any means or structure to the *apparatus* claims which defines over the applied prior art. This position is further explained below in the remarks section.

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Allowable Subject Matter

19. Claim 30-32 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 251 and to include all of the limitations of the base claim and any intervening claims.
20. Claims 1-21 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 251.

Response to Amendment

21. Applicant's arguments filed 10 SEP 2001 have been fully considered but they are not deemed to be persuasive.

Turning to the rejections of the claims under 35 U.S.C. § 102, it is noted that the terminology in a pending application's claims is to be given its broadest reasonable interpretation (*In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)) and limitations from a pending application's specification will not be read into the claims (*Sjolund v. Musland*, 847 F.2d 1573, 1581-82, 6 USPQ2d 2020, 2027 (Fed. Cir. 1988)). Anticipation under 35 U.S.C. § 102(b) is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of a claimed invention. See *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1064 (Fed. Cir.), cert. denied, 488 U.S. 892 (1988); *RCA Corp. v. Applied Digital Data Sys.. Inc.*, 730 F.2d 1440, 1444, 221 USPQ

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385, 388 (Fed. Cir. 1984). Moreover, anticipation by a prior art reference does not require either the inventive concept of the claimed subject matter or the recognition of properties that are inherently possessed by the prior art reference. *Verdegaal Brothers Inc. v. Union Oil co. of California*, 814 F.2d 628, 633, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987). A prior art reference anticipates the subject matter of a claim when that reference discloses each and every element set forth in the claim (*In re Paulsen*, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) and *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)); however, the law of anticipation does not require that the reference teach what Applicant is claiming, but only that the claims "read on" something disclosed in the reference. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984) (and overruled in part on another issue), *SRI Intel v. Matsushita Elec. Corp. Of Am.*, 775 F.2d 1107, 1118, 227 USPQ 577, 583 (Fed. Cir. 1985). Also, a reference anticipates a claim if it discloses the claimed invention such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention. See *In re Graves*, 69 F.3d 1147, 1152, 36 USPQ2d 1697, 1701 (Fed. Cir. 1995), *cert. denied*, 116 S.Ct. 1362 (1996), quoting from *In re LeGrice*, 301 F.2d 929, 936, 133 USPQ 365, 372 (CCPA 1962).

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With respect to the applied prior art under 35 U.S.C. § 102, the examiner has explicitly demonstrated how the references disclose each and every element set forth in the claims and how the pending claims read on the disclosures of the references, hence the rejections are still considered proper and are maintained.

Applicant argues that the prior art (e.g., to Raccuglia et al.) does not teach the particular holder as is recited in the claims. An analysis of claim 22 reveals the following structure: a centrifuge, a container with chambers, a bridge connecting the chambers, and a holder assembly attached to the centrifuge which removably receives the container. As noted above, the patent to Raccuglia et al. discloses a system in Figs. 8-11 comprising a centrifuge 212; a walled container 110, 112 (Figs. 8-9) having a first chamber 114 and a second chamber 116; a bridge 164,153, 152, 138 for transferring fluid between the chambers; and a holder assembly 214 attached to the centrifuge for removably receiving the container.

Applicant is reminded that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, *supra*. “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis test*, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d

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831, 15 USPQ2d 1566 (Fed. Cir. 1990). Since each and every element in claim 22 is disclosed by the patent to Raccuglia et al., the rejection under 35 U.S.C. § 102(b) is deemed proper within the statutory guidelines. Applicant contends that the holder of Raccuglia et al. is not capable of holding the container in a predetermined position, however, the claim language "wherein the holder assembly is effective to position the container on one or more predetermined positions" utterly fails to invoke any means or structure which further defines the holder assembly. Note, however, in stark contrast to such nearly meaningless functional language, claims 30-32 which actually do positively recite structure of the holder which functions to hold the container in a predetermined position have been deemed allowable!

The pith of Applicant's arguments are directed to functional, rather than structural distinctions between the claimed invention and the prior art. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danley*, 120 USPQ 528, 531 (CCPA 1959). "Apparatus claims cover what a device is, not what a device does." (emphasis in original).

Applicant's other major argument is that the prior art devices are not "sterile". The examiner's position is that the term "sterile" does not impart any specific structure to the container, but is perhaps a product by process limitation as to the manner in which the container is made or the manner in which the container is packaged (e.g., hermetically sealed to maintain sterility). However, the pending claims are strictly

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apparatus claims drawn to a centrifuge and/or container and no particular process for manufacturing the sterile container, sterilizing the container, or packaging for the container is set forth that either imparts sterility to or maintains sterility of the container. Hence, it is not clear how the physical structure of the container changes to define over the prior art simply by labeling it "sterile". Since the prior art anticipates the claimed subject matter, it appears Applicant expects allowance of the claims merely because the instant invention is sterile. Again, since sterility itself is not considered to impart any unique structural features to define over the applied prior art, allowance of the claims cannot be envisioned on this issue.

Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, 109 USPQ 34, (CCPA 1956). Although it would not impart patentability to the pending claims, it is noted Applicant has not provided any compelling evidence that the prior art containers are necessarily not sterile, whatever the metes and bounds of the term "sterile" purports to be.

Applicant further argues that some of the prior art has noting to do with medical products. However, "[e]xpressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not

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impart patentability to the claims." *In re Young*, 75 F.2d 966, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Accordingly, whether or not the prior art is intended for use with medical products or liquids or substances implemented in the medical field is immaterial to patentability.

In conclusion, the few amendments made in the instant application are not deemed of a substantive nature to define over the prior art and thus the rejections are considered proper and are maintained.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION. **ANY RESPONSE FILED AFTER THE MAILING DATE OF THIS FINAL REJECTION WILL BE SUBJECT TO THE PROVISIONS OF MPEP 714.12 AND 714.13.**

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Charles Cooley whose telephone number is (703) 308-0112.

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24. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1700 receptionist whose telephone number is (703) 308-0651.



Dated: 11 January 2002

Charles Cooley
Primary Examiner
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